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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/006,740 | 12/05/2001 | Alexander MacGregor | 23936-176 | 2553 |

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| EXAMINER | |
|---|---|
| FUBARA, BLESSING M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/006,740 | MACGREGOR, ALEXANDER | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-8,10-12,14-32,34,35 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,14-32,34,35 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks, all filed 11/30/05. Claim 36 is canceled. New claims 37-41 are added. Claims 1, 3-8, 10-12, 14-32, 34, 35 and 37-41 are pending.

### *Claim Rejections - 35 USC § 103*

1. The rejection of claims 1, 3-8, 10-32 and 34, 35 under 35 U.S.C. 103(a) as being unpatentable over Fritsch et al. (US 5,213,794) is withdrawn because, polycarbophil, a cross-linked acrylic polymer is cross linked with divinyl glycol while the claims require cross linking with allylsucrose or allylpentaerythritol and applicant's argument as it regards to cross linking acrylic polymer with allylsucrose or allylpentaerythritol is persuasive.

However, because polycarbophil and carbopol are both cross linked acrylic polymer and because both polycarbophil and carbopol are gelling agents and biodhesives, one gelling agent can be used in place of the other with the expectation of producing the desired gastric residence time. Thus an obviousness rejection over Fritsch in view of teaching that polycarbophil and carbopol are gelling agents (column 6, lines 36-41, US 6,596,763) and are bioadhesives (column 4, lines 36-38, US 6,200,604) is made below.

2. The rejection of claims 1, 3-8, 10-32, 34 and 25 under 35 U.S.C. 103(a) as being unpatentable over Rork et al. (US 5,582,838) is withdrawn because applicant's argument that Rork does not teach cross-linked polyvinyl pyrrolidone is persuasive. However, Rork suggest formulating ranitidine composition that comprises polyvinylpyrrolidone and carbopol. Ranitidine is also known in the art to be formulated with cross-linked polyvinylpyrrolidone (Example 4 of US 5,780,057).

***Response to Arguments***

3. Applicant's arguments filed 11/30/05, with respect to the rejection(s) of pending claims under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made is made below. The main issue of cross-linked polyvinylpyrrolidone and cross-linked acrylate that is cross linked with allylsucrose or allylpentaerythritol was addressed in the withdrawal of the rejections.

***Response to Amendment***

The amendment filed in response to the last office action introduced three further distinct inventions that required extensive search. The inventions are a) claims 37 where the hydrodynamic fluid imbibing polymer is selected from amylose, dextran, pullulan, ... which differ from the fluid imbibing polymer of claim 1; b) claim 38, which requires expansion source different from the expansion source of claim 8; c) claim 39 in which the expansion source differs from the expansion source of claims 38 and 8.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Bai (US 5,840,329).

Bai discloses a dosage form that comprises dextran, which is hydrodynamic fluid-imbibing polymer recited in claim 37 b) i), cross-linked polyvinylpyrrolidone, which is hydrostatic pressure modulating agent of claim 37 b) ii) (see claims 1, 4, 13 and 15). Bai meets the limitations of claim 37.

6. Claims 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Dresdner, Jr. et al. (US 5,357,636).

Dresdner, Jr. discloses antiseptic composition comprising antiseptic agents such as povidone iodine, sodium hypochlorite, nonoxynol 9 and chlorhexidine gluconate, sodium dichloroisocyanurate, sodium perborate, to name a few (abstract; column 12, lines 50-67; column 27, lines 39-53; column 27, lines 40-50), surfactant (column 13, line 1), antibiotics (column 27, line 65 to column 28), bicarbonate or peroxide (column 30, line 51 to column 31 line 41), viscosity modifying polymer/agent such as cross-linked polyvinylpyrrolidone and carbopol (column 35, line 56 to column 36 line 37). The teaching of Dresdner, Jr. meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 3-8, 10-12, 14-32, 34, 35, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritsch et al. (US 5,213,794) in view of Thormar et al. (US 6,596,763) or Pather et al. (US 6,200,604).

Fritsch discloses a tablet formulation that comprises polyacrylic acid/methacrylate copolymer, polyvinylpyrrolidone, propylene glycol, calcium polycarbophil, crospovidone, silica, saccharin sodium, banana flavoring and calcium stearate (example 1 and column 6, lines 34-53). The combination of polyvinylpyrrolidone and the acrylate polymer is equivalent to the hydrostatic couple of the instant claims. The active ingredient in Fritsch is antacid (abstract and Examples 1 and 2). There is no demonstration in the instant specification that the ratio of the hydrodynamic fluid-imbibing polymer to the hydrostatic pressure modulating as is recited in the instant claim 1 confers unusual characteristic results to the delivery system. Differences in amounts or concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such amount or concentration is critical. And "[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). One having ordinary skill in the art would have the skills to use appropriate amounts of the hydrodynamic fluid-imbibing polymer and hydrostatic pressure modulating with the expectation of delivering the active agent of choice.

Fritsch discloses a composition comprising polycarbophil, a crosslinked acrylate polymer, but the polycarbophil differs from a crosslinked acrylate that is cross linked with allylsucrose or allylpentaerythritol. Thormar or Pather discloses that polycarbophil and carbopol are gelling agents (column 6, lines 36-41, US 6,596,763) and are bioadhesives (column 4, lines 36-38, US 6,200,604). One gelling agent or bioadhesive can be substituted for by another. Therefor, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the dosage of Fritsch using polycarbophil and carbopol. One

having ordinary skill in the art would have been motivated to substitute carbopol for the polycarbophil of Fritsch with the expectation of producing dosage form having the desired gastric retention time. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

9. Claims 1, 3-8, 10-12, 14-32, 34, 35, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al. (US 5,582,838) in view of Conte et al. (US 5,780,057). Rork discloses a tablet formulation (column 7, lines 21-42) comprising pharmaceutically active ingredients such as antimicrobials, local anesthetic, analgesics and anti-inflammatory agents (column 6, lines 18, 20, 24 and 18), excipients such as lactose, magnesium stearate, polyvinylpyrrolidone and dyes (column 8, lines 13-25), CARBOPOL polymer (column 8, lines 45-65) and carbonate (claims 10). See also column 13, line 20 to column 14, line 9). The combination of the CARBOPOL and the polyvinylpyrrolidone constitutes the hydrostatic couple of the instant application. The carbonate is the carbon dioxide precursor of the instant application. Rork teaches particulate formulation (column 8, lines 21-25) and the pharmaceutically active agents are present in amounts of from about 0.01% to about 75% of the core weight (column 8, lines 26-32). Rork does not disclose cross-linked polyvinylpyrrolidone. Ranitidine is one of the active agents in Rork (column 6, line 55). Conte discloses ranitidine composition that contains cross-linked polyvinylpyrrolidone (Example 4).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the

very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, Conte and Rork disclose ranitidine containing composition. Therefore, it would have been obvious to on of ordinary skill in the art at the time the invention was made to prepare the ranitidine composition of Rork. One having ordinary skill in the art would have been motivated to prepare a third composition comprising ranitidine, cross-linked polyvinylpyrrolidone, polyvinylpyrrolidone and carbopol with the expectation that this third composition when administered would function as ranitidine dosage form for inhibiting gastric ulcer secretion in ulcer patients. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
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